UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
McALLEN DIVISION

ROY ECKHARDT and YOLANDA C. ECKHART, Plaintiffs, v. QUALITEST PHARMACEUTICALS, INC.; WYETH, INC., individually and as successor-in-interest to A.H. ROBBINS COMPANY, INC. and AMERICAN HOME PRODUCTS; SCHWARZ PHARMA, INC.; and VINTAGE PHARMACEUTICALS, LLC; Defendants.	§ § § § § § § § § § § § § §	CASE NO. 7:11-cv-00235

PLAINTIFFS' RESPONSE AND MEMORANDUM IN OPPOSITION TO DEFENDANTS QUALITEST PHARMACEUTICALS, INC. AND VINTAGE PHARMACEUTICALS, LLC'S MOTION TO DISMISS

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I. STATEMENT OF THE ISSUES TO BE RULED UPON BY THE COURT

This matter comes before the Court on Defendants Qualitest Pharmaceuticals, Inc and Vintage Pharmaceuticals, LLC's (hereinafter referred to collectively as "Generic Defendants") Motion to Dismiss. [Doc. 47]. The issue to be ruled upon by the Court is whether Plaintiffs' claims against a generic manufacturer based on theories of negligence, suppression of evidence, fraud, strict liability, breach of warranty and deceptive trade practices are preempted by the Supreme Court's decision in *PLIVA, Inc. v. Mensing.* A motion to dismiss should not be granted unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief. *Campbell v. Wells Fargo Bank, N.A.,* 781 F.2d 440, 442-43 (5th Cir. 1986). In deciding a motion to dismiss, a district court is required to accept as true all well pleaded facts in the complaint; and the complaint is to be liberally construed in favor of the plaintiff. *Id;* citing *Abdul Alim Amin v. Universal Life Insurance Co. of Memphis,* 706 F.2d 638, 640 (5th Cir.1983).

II. SHORT STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDING

Plaintiffs filed their Second Amended Complaint on August 26, 2011 to recover for personal injuries she has suffered as a result of being prescribed and ingesting the prescription drug Reglan/metoclopramide. [Doc. 22, ¶3.01]. On September 30, 2011, Generic Defendants filed a Motion to Dismiss asserting that all of Plaintiffs' claims are preempted by the U.S. Supreme Court's decision in *Pliva, Inc. v. Mensing,* 564 U.S. ____, 131 S.Ct. 2567 (June 23, 2011). [Doc. 47]. Plaintiffs file this brief in response to Generic Defendants' Motion to Dismiss.

III. SUMMARY OF THE ARGUMENT

Generic Defendants argue that the US Supreme Court's decision in *Mensing* mandates the dismissal of all of Plaintiffs' claims and ask the Court to find that since they could not have added new or different information to the labeling of its metoclopramide products, that it is entitled to blanket immunity from liability. Contrary to Generic Defendants' assertions, a review of the *Mensing* decision and the numerous allegations in Plaintiffs' complaint show that the Court's decision affects only one theory of liability, and that the numerous other theories advanced by Plaintiffs remain viable causes of action. For the reasons below, Plaintiffs therefore respectfully request that Generic Defendants' Motion be denied.

On June 23, 2011, the Supreme Court of the United States issued its opinion in *PLIVA, Inc. v. Mensing.* The *Mensing* decision determined that federal law preempts state law failure-to-warn actions based on a theory that a generic drug manufacturer should have changed the content of its label. As Plaintiffs have alleged theories of liability which are different than the single claim considered by the court in *Mensing,* the decision is entirely distinguishable with regard to its finding of preemption.

Importantly, the *Mensing* decision indicates that generic manufacturers *are* required to monitor the safety of their drug products once they enter the marketplace, and that federal law *requires* them to take certain action if and when they have concerns regarding the safety of their drugs. As Plaintiffs allege that Generic Defendants did not comply with their duty to monitor the safety of their drug, opting instead to remain willfully ignorant of the risks metoclopramide posed to consumers, and did nothing to correct the problem they were creating, claims under such theories (in addition to others) are not preempted. Additionally, *Mensing* did not consider

the impact of additional warnings added to the label for metoclopramide in 2004 designed to prohibit long-term use, and a generic drug manufacturer's duty to inform physicians and consumers about information already appearing in the approved labeling for the drug. In addition to its many other failures, Generic Defendants failed entirely to alert Plaintiff or his physicians to the existence of these warnings both prior to and during the time that Mr. Eckhardt consumed Generic Defendants' products.

The *Mensing* decision bears only on one aspect of a drug label's adequacy – its content. In order to be adequate, a manufacturer's warning must be judged not only by its content, but also by the manner in which it is communicated. In the present case, Generic Defendants never provided Plaintiff or his physicians with ANY warning or other information with regard to metoclopramide. Generic Defendants' total failure to provide physicians with any warning or instruction for proper use of their drug, rendered highly relevant in light of changes made to the label for metoclopramide prohibiting long-term use, was an issue not before the *Mensing* Court, and the decision does not preclude claims based on such a theory.

IV. LAW AND ARGUMENT

A. PLAINTIFFS' COMPLAINT

Accepting all of the allegations contained in the complaint as true, and viewing them in the light most favorable to Plaintiffs, the facts can be summarized in the following way:

At the time that Generic Defendants began manufacturing and selling metoclopramide, they were fully aware of the fact that the labeling for the drug lacked information necessary for the safe and effective use of the drug. *Id* at ¶¶ 3.39-40, 53-56, 64, 72-76, 78. Not only did Generic Defendants know that the label lacked adequate instructions for use, they were also aware of the fact that their label contained false information which understated the risk of

developing serious side effects by orders of magnitude. *Id.* They were also aware that the FDA had based approval of the drug on false and unscientific information, and that the drug was neither safe nor effective in treating those conditions for which it was being prescribed. *Id.*

Even further, Generic Defendants encouraged physicians and consumers to prescribe and ingest metoclopramide in a manner that was likely to result in severe injury. *Id* at ¶¶ 3.52, 54-56, 63-64, 72-76, 78, 82, 93-94. During the time that Generic Defendants were manufacturing and selling metoclopramide,they received further reports from qualified researchers that the label for metoclopramide vastly underestimated the dangers associated with use of the drug beyond 12 weeks, and that over one-third of the prescriptions being written for the drug were for periods longer than *one year*. *Id* at ¶¶ 3.75-76. Fearing that the information would result in reduced sales, Generic Defendants concealed this information from the FDA, physicians and consumers, and represented and warranted instead that there was, in fact, no appreciable danger with metoclopramide use, and that use of the drug for periods longer than 12 weeks was entirely acceptable and safe. *Id* at ¶¶ 3.52, 54-56, 63-64, 72-76, 78, 82, 92-94, 98-106.

In 2004, when Schwarz Pharma, Inc., the Reference Listed Drug ("RLD") holder for metoclopramide changed the labeling for the drug to include a prohibition on long-term use, Generic Defendants were aware of the fact that the important new safety information had not been provided to physicians or consumers. *Id* at ¶¶ 3.71, 82, 86, 95, 96, 101, 103-106. Instead of alerting these individuals to the fact that therapy with the drug should not exceed 12 weeks in duration, Generic Defendants again concealed both its label and the new prohibition it contained from physicians and consumers. *Id.*

As set forth below, accepting these allegations as true, it is clear that Generic Defendants had numerous means at its disposal that could have prevented plaintiff's injuries, only one of

which was to change the content of its labeling. As Plaintiffs have alleged that Generic Defendants sold their drug with knowledge that the safety information contained within the label was false, that Generic Defendants were aware of the fact that physicians and patients were prescribing and using their drug based on the false information and inadequate instructions they provided (or failed to provide), and that they concealed the fact that long-term use of metoclopramide was unlikely to be safe in spite of FDA-approved warnings indicating that use of the drug should not exceed 12 weeks in duration, Plaintiffs' complaint identifies numerous theories of liability that were not considered by the *Mensing* Court.

B. THE *MENSING* DECISION

Generic Defendants' Motion mistakenly argues that the claims before the Court in *Mensing* are indistinguishable from those alleged by Plaintiffs in the present case. It is abundantly clear from the Court's ruling in *Mensing* that the issue it decided was a narrow one – whether a state law requirement that a generic drug manufacturer change the contents of its label was preempted by the federal requirement that generic labeling match that of the Reference Listed Drug ("RLD"). The Court made clear that it was making no determination of what state law required of a manufacturer, but rather acknowledged that "the parties [did] not dispute" that the laws of Louisiana and Minnesota required a generic manufacturer to change their label to meet the duties imposed by state law. *Mensing,* 131 S.Ct at 2574. While *Mensing* does affects one theory of liability that may be asserted against a generic drug manufacturer, it is by no means dispositive of all of Plaintiffs' claims.

The United States Supreme Court has consistently and repeatedly rejected an approach to preemption such proposed by Generic Defendants - that all causes of action are preempted by

federal law simply because particular claims are preempted.[2] As discussed below, the Court's decision in *Cipollone v. Liggett Group, Inc.* rejected the notion that the descriptive label attached to a particular claim determines whether it is preempted. 505 U.S. 504, 521 (1992). In resolving preemption issues, a Court must undertake a preemption analysis whereby it scrutinizes the duty imposed by each of a plaintiff's state law claims before it determines which are preempted. *Id; see also Spain v. Brown and Williamson Tobacco Corp.,* 363 F.3d 1183, 1193 (11th Cir. 2004); *Wright v. Brooke Group Ltd.*, 114 F. Supp. 2d 797, 824 (N.D. Iowa 2000); *LaBelle v. Brown & Williamson Tobacco Corp.*, 2:98-3235-23, 1999 WL 33591435 (D.S.C. 1999). In *Mensing*, the Court found there to be "impossibility preemption" – that it would have been impossible for a generic manufacturer to change its label and thereby comply with both state and federal law. Whether specific state law claims will be preempted thus depends on whether there is an "actual conflict" between the requirements of the state and the federal government. *See e.g. English v. General Electric Co.,* 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143.

It follows from the above that in order to perform a preemption analysis on the claims asserted by Plaintiff, one must first determine what federal law requires, what is required under state law, and the extent to which those requirements conflict. The Court in *Mensing* stated the issue before the Court as follows:

> To summarize, the relevant state and federal requirements are these: State tort law places a duty directly on all drug manufacturers to adequately and safely label their products.

[2] *See, e.g., Cipollone v. Liggett Group, Inc.,* 505 U.S. 504 (1992) (plaintiff's failure to warn claims imposing requirements "different or in addition to" those required by federal law were preempted, whereas plaintiff's negligent failure to warn, express warranty, fraud, misrepresentation, and conspiracy claims survived); *Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005) (remanding plaintiff's failure to warn and fraud claims to determine conflict with state law, but finding no preemption with regard to plaintiff's defective design, defective manufacture, negligent testing, breach of express warranty, or violation of consumer protection statute claims); *Altria Group Inc., v. Good,* 555 U.S. 70 (2008) (affirming *Cipollone,* and finding claims based on violation of state's unfair trade practice statute not preempted).

> Taking Mensing and Demahy's allegations as true***, this duty required the manufacturers to use a different, stronger label than the label they actually used***. Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. But, we assume, federal law also required the Manufacturers to ask for assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well.

Mensing, 131 S. Ct. at 2577 (emphasis added).[3] Thus, the finding of preemption in *Mensing* is premised upon an allegation that state law would require a manufacturer to actually the change the content of its label. The Court based its finding of preemption on the fact that state law would have required defendants to provide different, additional warnings than appeared in the labeling for the reference listed drug ("RLD"), and that it was impossible to do so under federal law, as a generic drug's label is required to be the same as the RLD. When considered in the context of other Supreme Court precedent, including the Court's finding in *Wyeth v. Levine*, 555 U.S. 555 (2009), that there are no broader preemption principles at issue, it is clear that the narrow legal situation described in *Mensing* (where a state's law requires the specific action of changing the content of the label for a prescription drug) is irrelevant to the majority of the theories of liability presented in Plaintiffs' complaint.

In addition to its finding of preemption as described above, the *Mensing* Court also acknowledged that generic manufacturers have a duty to keep abreast of information regarding their drug's effect on consumers in the marketplace, and that they must take action (notifying the FDA and/or brand-name manufacturer) when there is evidence that its drug may be harming people. While *Mensing* was pending before the Supreme Court, the FDA stated its official position on the interpretation of applicable regulations in an *amicus curiae* brief filed at the

[3] The *Mensing* Court also noted that the parties did not dispute that the only law at issue was a state law that "required the Manufacturers to use a different, safer label." *Id* at 2574.

request of the Court. 2011 WL 741927 (U.S. 3/2/2011). The Court based its decision in *Mensing* on the fact that the FDA indicated in its brief that generic manufacturers were not allowed to unilaterally change the contents of their package inserts to provide different or additional warnings.

That is not all that the FDA's brief stated, however - it also stated that generic manufacturers DO have a duty to monitor the safety of their drugs in the medical and scientific literature, to review the labeling for their drug products to determine if it is adequate and accurate, and to inform the FDA of labeling deficiencies so that the agency might take appropriate action. Specifically, the agency stated the following:

> Information on the risks and benefits associated with a drug may accumulate over time. Accordingly, NDA and ANDA holders must keep records of clinical experiences and ensure that their drugs remain safe and effective as labeled. In particular, implementing regulations provide that a manufacturer must record and report certain adverse events to FDA, and must also annually report a summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product and a description of actions the applicant has taken or intends to take as a result of that new information.

Id at pg. 6 (internal citations omitted). The FDA characterized the actions required of a generic manufacturer as follows:

> FDA regulations require NDA holders and ANDA holders alike to act upon new safety information that warrants added or strengthened warnings. Petitioners are correct that, in meeting that federal duty, they could not properly have invoked the CBE or PAS process, or sent the sort of DHCP letter respondents envision. But ANDA holders nonetheless should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

Id at pg. 12. Plaintiffs have alleged that Generic Defendants did NOTHING to comply with these obligations.

Generic Defendants' Motion argues that even though they failed entirely to meet duties imposed upon them by both state and federal law, they should be exempt from all liability

because they could not have unilaterally changed the contents of their label. A reading of Plaintiffs' complaint makes it clear that Plaintiff has alleged not only that Generic Defendants failed to change the content of their label, but also that their label contained false information, that Generic Defendants failed to *communicate* existing warnings to the medical community, and that Generic Defendants "failed to use reasonable care" in *providing* warnings, in addition to other allegations. There is simply no support for Generic Defendant's proposition that all such claims are preempted under *Mensing.* To the contrary, *Mensing* states that federal law requires the label for a generic drug to be the same as the RLD, so that any claim brought by a Plaintiff which is based on a generic manufacturer's failure to change the content of their label (one type of "failure-to-warn" claim) would be preempted. *Mensing* says absolutely nothing about a manufacturer's duty to *provide* a warning (i.e. communicate information appearing in FDA-approved labeling to physicians or consumers), to *discover and report* the risks associated with its product, nor does it speak to the other causes of action asserted by Plaintiff.

C. PREEMPTION AND FEDERAL LABELING REQUIREMENTS

As the Court's decision in *Mensing* dealt only with claims based on the alleged deficiency of the contents of a product's labeling, the decision must be read in conjunction with other pronouncements the Court has made with regard to preemption of claims based on a product's labeling. The guidance offered by these cases clearly shows that the majority of the claims asserted by Plaintiff remain intact when considering in light of *Mensing.*

While a specific statute or regulation may be found to preempt certain state laws, such a finding says nothing about the *scope* of that preemption. *Bates,* 544 U.S. at 433-434. In cases where express pre-emption is at issue, the scope of the preemption is determined by the language of the statute. *Cipollone,* 505 U.S. at 516; *Bates,* 544 U.S. at 433-434. In cases of conflict

preemption, a state's laws are preempted only to the extent such law conflicts with the federal law. *See Geier v. American Honda Motor Co., Inc.,* 529 U.S. 861, 884 (2000). With regard to impossibility preemption, which the Court found to exist in *Mensing,* and which Generic Defendants' Motion argues applies to the claims at issue here, state law is preempted only to the extent that it is "impossible for a private party to comply with both state and federal requirements." *Mensing,* 131 S.Ct. at 2577, quoting *Freightliner Corp. v. Myrick,* 514 U.S. 280, 287 (1995). In determining any pre-emption issue, a court is to be guided by the "two cornerstones" of pre-emption jurisprudence:

> First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' "

Wyeth v. Levine, 555 U.S. 555 (2009) (internal citations omitted).

The Supreme Court has recognized that while the common law does not normally require a vendor to use any specific statement on its packages or advertisements, it does serve to enforce duties that constitute either "affirmative *requirements*" or "negative *prohibitions*" contained in those laws. *Cipollone,* 505 U.S. at 522 (emphasis in original). A "requirement" such as considered by the *Mensing* Court, is a rule of law that must be obeyed; an occurrence that merely motivates an optional decision by a manufacturer (such as the rendering of a jury verdict) does not qualify as a requirement. *Bates,* 544 U.S. at 444.

Furthermore, where a state law "prohibition" restricts activities that are only *permitted* by the federal government, and not *required,* no conflict exists. *See Florida Lime & Avocado Growers, Inc., v. Paul,* 373 U.S. 132, 144-145, citing *Cloverleaf Butter Co. v. Patterson,* 315 U.S. 148 ("a State might nevertheless – at least in the absence of an express contrary command

of Congress – confiscate or exclude from market the processed butter which had complied with all federal processing standards, 'because of a higher standard demanded by a state for its consumers.'"); *see also Barnett Bank v. Nelson*, 517 U.S. 25 (1996) (finding no impossibility preemption to exist where a federal statute permitted national banks to sell insurance in small towns, but a state statute prohibited the same activity). As stated by the Court, "Congressional regulation of one end of the stream of commerce does not, ipso facto, oust all state regulation at the other end." *Florida Lime & Avocado Growers, Inc.*, 373 U.S. at 1219. As a result, if the generic defendants could have complied with any of their duties under state law by taking actions other than changing the content of its label (such as refraining from putting its metoclopramide on the market, which neither federal nor state law required it to do), a claim based on such law would not be preempted.

1. *Cipollone v. Liggett Group, Inc.*[4] and *Altria Group, Inc. v. Good*[5]

The first instance in which the Supreme Court had the opportunity to consider the preemptive effect of state law claims as they specifically relate to federally regulated labeling was in *Cipollone v. Liggett Group, Inc.* The federal statute at issue in *Cipollone* was the Federal Cigarette Labeling and Advertising Act, as amended by the Public Health Cigarette Smoking Act of 1969. *Id* at 510. There was an express preemption provision in the federal law which provided that "[n]o statement relating to smoking and health, other than the statement required by [federal law] shall be required on any cigarette package." *Id* at 514. In addition to the prohibition on any requirements for statements appearing on the packages themselves, federal law also preempted states from including different or additional statements in the advertising or promotion of cigarettes, which were also considered labeling. *Id.*

[4] 505 U.S. 504 (1992)
[5] 555 U.S. 70 (2008)

In a plurality opinion, the Supreme Court divided the claims asserted by the plaintiff into five categories (1) design defect claims, (2) failure to warn claims, (3) negligence claims (including negligent failure to warn), (4) express warranty claims, and (5) fraudulent misrepresentation claims. *Id* at 511. The District Court had found all except the design defect claims to be preempted. *Id* at 512. Before analyzing each of these categories, the Court began by acknowledging the fact that federal law requires a particular warning label for a product "does not by its own effect foreclose additional obligations imposed under state law" and that "there is no general, inherent conflict between federal preemption of state warning requirements and the continued validity of state common-law damages actions." *Id* at 518. The Court then undertook to analyze each of the asserted claims in order to determine whether they were preempted.

With regard to plaintiff's failure-to-warn claims, the Court separated the claims that alleged that defendants "failed to provide 'adequate warnings of the health consequences of cigarette smoking'" from those alleging that defendants "were negligent in the manner [that] they tested, researched, sold, promoted, and advertised their cigarettes." *Id* at 525. With respect to Plaintiff's failure-to-warn claims, the Court found:

> Thus, insofar as claims under either failure to warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings, those claims are pre-empted. The Act does not, however, pre-empt petitioner's claims that rely solely on respondents' testing or research practices or other practices unrelated to advertising or promotion.

Id.

Next, the Court determined that plaintiff's breach of express warranty provisions were not preempted by federal law. In finding no preemption, the Court rejected the finding of the District Court that since the warranty at issue consisted solely of statements appearing in defendant's advertising, that the breach of warranty claim would "inevitably bring into question

[respondents'] advertising and promotional activities," and that the claim was therefore preempted. *Id* at 525. The Court stated that the proper inquiry "is not whether a claim challenges the 'propriety' of advertising and promotion, but whether the claim would require the imposition under state law of a requirement or prohibition based on smoking and health." *Id.* The Court went on to state as follows:

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the 'requirement[s]' imposed by an express warranty claim are not "imposed under state law," but rather imposed *by the warrantor*… In short, a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement… imposed under State law" within the meaning of [the Act].
>
> That the terms of the warranty have been set forth in advertisements rather than in separate documents is irrelevant to the pre-emption issue… because, although the breach of warranty claim is made "with respect … to advertising," it does not rest on a duty imposed under state law. Accordingly, to the extent that petitioner has a viable claim for breach of express warranties made by respondents, that claim is not preempted by the 1969 Act.

With regard to the fraudulent misrepresentation claims advanced by the plaintiff, the Court found those claims to be preempted to the extent plaintiff were alleging that these statements "negate or disclaim" the warnings required under federal law. *Id* at 527-528. The Court also determined, however, that plaintiff's misrepresentation claims alleging that defendants made false representations of material fact and/or concealed material facts were not preempted:

> Petitioner's claims that respondents concealed material facts are therefore not pre-empted insofar as those claims rely on a state-law duty to disclose such facts through channels of communication other than advertising or promotion. Thus, for example, if state law obliged respondents to disclose material facts about smoking and health to an administrative agency, § 5(b) would not pre-empt a state-law claim based on a failure to fulfill that obligation.
> …
> State-law prohibitions on false statements of material fact do not create "diverse, nonuniform, and confusing" standards. Unlike state-law obligations concerning the

> warning necessary to render a product "reasonably safe," state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity.

Id at 528-29. The Court then found that plaintiff's conspiracy claims were not preempted for the same reasons that it did not find their fraudulent misrepresentation claims to be preempted.

As stated above, the analysis employed by the Court in *Cipollone* was only subscribed to by a plurality of the justices. In 2008, however, the Court issued another decision with regard to the same federal law at issue in *Cipollone.* In *Altria Group, Inc. v. Good* a majority of the Court rejected the argument advanced by defendants that plaintiff's claims of fraud and violation of a state's Unfair Trade Practices Act were disguised failure-to-warn claims. *Altria,* 555 U.S. at 545-546 ("To be sure, the presence of the federally mandated warnings may bear on the materiality of petitioners' allegedly fraudulent statements, 'but that possibility does not change respondents' case from one about the statements into one about the warnings"). In doing so, the Court adopted the analysis employed by the plurality in *Cipollone.*

2. *Bates v. Dow Agrosciences LLC*[6]

In the time between the *Cipollone* and *Altria* decisions discussed above, the Supreme Court rendered another decision involving preemption in the context of federal labeling requirements. In *Bates v. Dow Agrosciences, LLC,* 544 U.S. 431 (2005), the statute at issue was the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Farmers in Texas brought numerous state law causes of action against Dow Agrosciences for damage caused by a pesticide which had been labeled in compliance with federal law. *Id.* Much the same as the FDCA provisions at issue in *Mensing,* FIFRA contained an express preemption clause which preempted any claims brought under state law which would "impose or continue in effect any requirements

[6] 544 U.S. 431 (2005).

for labeling or packaging in addition to or different from those required" by federal law. *Id* at 442.

Adhering to the analytical framework announced in *Cipollone* and *Altria*, the Supreme Court rejected the defendant's argument that a jury verdict brought under any cause of action would be preempted because a successful claim would "induce" a manufacturer to change its label, thereby achieving the same end as a failure-to-warn claim. *Id* at 443. The Court stated:

> For a particular state rule to be pre-empted, it must satisfy two conditions. First, it must be a requirement "*for labeling or packaging*"*;* rules governing the design of a product, for example, are not pre-empted. Second, it must impose a labeling or packaging requirement that is "*in addition to or different from* those required under this subchapter." A state regulation requiring the word "poison" to appear in red letters, for instance, would not be pre-empted if an EPA regulation imposed the same requirement.

Id at 444. The court went on to announce that it was "perfectly clear" that many of the common law rules which served as the basis for plaintiff's claims did not satisfy the first condition. In the words of the Court:

> Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for "labeling or packaging." None of these common-law rules requires that manufacturers label or package their products in any particular way. Thus, petitioners' claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not pre-empted.

Id.

The Court went on to acknowledge that the express warranties identified by the plaintiff were located in the text of the label for Dow's product, and that failure-to-warn claims based on the adequacy of such labeling would be pre-empted. The Court found however, that a cause of action for breach of an express warranty requires only "that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing the warranty on its product." *Id.*

The Court found that because the common-law rule did not require the manufacturer to make the express warranty (i.e., to sell the product), and the fact that the common-law rule did not require any specific warranties to be made, that it was not preempted under FIFRA. *Id.*

With regard to Dow's argument that a finding of liability on any of those claims would "induce Dow to alter [its] label," the Court stated the following:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue, see *Cipollone*, 505 U.S., at 524, 112 S.Ct. 2608 (plurality opinion); it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Bates, 544 U.S. at 445.

The *Bates* Court also reaffirmed the availability of so-called "parallel claims" – causes of action brought under provisions of state law that enforce requirements imposed by federal law:

> Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA. Unlike the cigarette labeling law at issue in *Cipollone*, which prescribed certain immutable warning statements, FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings. As one court explained, tort suits can serve as a catalyst in this process:
>
> By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides such as [the pesticide at issue], a state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides. Successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labeling of their products; alternatively, EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits. In addition, the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.

Id at 451, *quoting Ferebee v. Chevron Chemical Co.,* 736 F.2d 1529, 1541-1542 (C.A.D.C. 1984). The Supreme Court has stated that the same justification exists for allowing tort claims to proceed against pharmaceutical manufacturers. *See Wyeth v. Levine,* 555 U.S. 555 (2009)[7].

The *Cipollone, Bates* and *Altria* cases makes it clear that *Mensing* only serves to preempt certain state law actions based on a theory that would require the defendant to change the content of their label to differ from that of the RLD. All other causes of action remain unaffected. Furthermore, any claims that do not require plaintiff to show that the generic manufacturer was required to provide a warning with content that differed from the labeling of the RLD would not be preempted for the reasons stated above.

D. OTHER FEDERAL LAW REQUIREMENTS

1. The FDCA and Misbranding

As the Supreme Court has acknowledged, the since its inception, the FDCA has "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs" and "supplement[s] the protection of consumers already provided by state regulation and common-law liability." *Wyeth v. Levine,* 129 S.Ct. at 1195-1196 (2009). As noted by the Solicitor General in its amicus brief, "a drug is 'misbranded' in violation of the FDCA when its labeling is false or misleading, or does not provide adequate directions for use and adequate warnings." 2011 WL 741927 at *3 (internal citations omitted). Under the FDCA, a manufacturer may not

[7] "The FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation."

introduce into commerce a misbranded drug. 21 U.S.C. 331(a).[8] In addition to prohibiting manufacturers from selling or distributing a misbranded drug into interstate commerce, the FDCA also requires a generic manufacturer to take action when it believes its labeling is inadequate or inaccurate. *Id* at *26, ("… federal law requires a manufacturer to act to update its labeling.."). The Solicitor General also found that allegations such as Plaintiff's, that a generic manufacturers' drug labeling understated the risks associated with a drug and lacked adequate directions for use, were the equivalent of alleging the drug was misbranded :

> In addition to whatever claim those allegations state under state law, they would also establish that petitioners' metoclopramide products were misbranded under 21 U.S.C. 352(f)(2) because those drugs would lack adequate warnings, and petitioners would have failed to discharge their duty under Section 201.57(e) to seek a revision to their approved labeling in light of newly acquired information not previously considered by FDA.

Id at *30.

Neither the Solicitor General's *amicus* brief or the Court's decision in *Mensing* addressed the ability of a Plaintiff to assert liability against a generic drug manufacturer for continuing to manufacture and distribute its drug, despite the fact that it is misbranded. In fact, both the Solicitor General's brief, and the *Mensing* opinion acknowledged that Plaintiff had not advanced such an argument.[9] *Id* at 25; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2588 (2011). As a result, it cannot be said that this theory of liability is precluded by the Court's decision.

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[8] The FDCA describes the acts it prohibits to include"[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

[9] "Drugs with FDA approval are presumptively lawful to sell in commerce. Respondents do not contend otherwise or suggest that petitioners' drugs simply should not have been available on the market." *Amicus* brief; "In its decision below, the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product"); see also *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (describing "a case of impossibility" as one "in which state law penalizes what federal law *requires* " (emphasis added)). Respondents have not advanced this argument, and I find it unnecessary to consider." *Mensing.*

2. Communication of Drug Safety Information

In 1996, Congress joined FDA in recognizing problems regarding the ineffective communication of important information regarding prescription drug products, and directed the pharmaceutical industry and other stakeholders to develop a long-range comprehensive action plan to achieve goals consistent with FDA's proposed rule.[10] The FDA has consistently reinforced this policy of achieving effective communication of prescription drug information.[11] In providing guidance regarding the dissemination of information to the public, FDA has, for example, suggested that "sponsors also use various methods to communicate drug safety information." For example, a sponsor may distribute a 'Dear Health Care Professional' letter (sometimes referred to as a "Dear Doctor" letter) to convey important information regarding a marketed drug. ***A sponsor may issue a Dear Healthcare Professional letter on its own initiative*** or following a request by the FDA."[12] The FDA explained that "Dear Healthcare Professional letters may be used to disseminate information regarding a significant hazard to health, ***to***

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[10] *See* Pub. L. 104-180. In response to Congress' directive, a committee including representatives of the pharmaceutical industry submitted a plan to the Secretary of the Department of Health and Human Services in December, 1996. *See* Action Plan for the Provision of Useful Prescription Medicine Information, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/Reports Budgets/UCM163793.pdf.

[11] *See, e.g.*, Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (2009), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ Guidances/ UCM155480.pdf.

[12]Guidance: Drug Safety Information – FDA's Communication to the Public (2007), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/_____ (emphasis supplied, internal citations omitted).

While *Mensing* determined that a generic manufacturer could not send "Dear Doctor Letters" that contained different or additional warnings, the Court did not consider whether a generic manufacturer could send such a letter to alert of recent FDA-approved changes, such as the prohibition on long-term use added to the Reglan label in 2004, which the Solicitor General's *amicus* brief indicated would be appropriate. *See also Keck v. Endoscopy Center of Southern Nevada*, Case No. A57837, Order dated 8/19/2011, attached as Exhibit A (finding that claims that a generic manufacturer should have sent "Dear Doctor Letters" that were "consistent and not contrary to" FDA-approved labeling were not preempted under *Mensing*); *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc.*, CA No. 10-00031 (S.D. Ala), Order dated 9/12/11, attached as Exhibit B (same).

announce important changes in product labeling, or to emphasize corrections to prescription drug advertising or labeling." *Id*. (emphasis supplied).

Clearly, generic drug manufacturers' disseminating **NO INFORMATION AT ALL** regarding metoclopramide to either prescribers or patients is contrary to federal policy and guidelines. Generic drug manufacturers not only could and should have widely ***disseminated*** the information contained in updated, FDA-approved labeling, but according to related FDA guidelines, they ***independently*** could and should have done much more. FDA has indicated that the process of risk minimization should be continually performed by the manufacturer as long as their drug is on the market.[13] FDA also advises manufacturers that they should consider input from health care professionals and consumers when assessing risk and when considering taking actions designed to minimize this risk. *Id.*

In providing guidance, FDA has identified numerous means of communication all drug manufacturers can and should take to minimize an identified risk ***besides a change in labeling***.[14] FDA points to the lack of effectiveness of labeling changes alone to address identified risks as one rationale for advocating the use of these tools.[15] Some of the other means that have been long available to a generic manufacturer to minimize an identified risk are: (1) training programs for healthcare practitioners or patients; (2) continuing education for healthcare practitioners; (3) prominent professional or public notifications; (4) promotional techniques such as direct-to-consumer advertising highlighting appropriate patient use or product risks; (5) patient-sponsor

[13] Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (2005), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf.

[14] Guidance for Industry: Development and Use of Risk Minimization Action Plans (2005) ("RiskMAP Guidance"), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071616.pdf.

[15] *Id.* at 12-13.

interaction and education systems such as disease management and patient access programs; and (6) specialized packaging to enhance safe use of the product. *Id; see also, id* at 6, n. 7.

Federal policy is, therefore, clear and unequivocal – manufacturers must ensure that information regarding the safety and efficacy of prescription drugs reaches those who prescribe, dispense and ingest these drugs. *Mensing* does not address or bar claims where a drug manufacturer has provided inadequate notice of information already appearing in FDA-approved labeling. Nor does it preempt any claim where the manufacturer could have satisfied its duty under state law by approaching the FDA with information supporting a label change for metoclopramide, or by suspending sales of its drug. Instead, it addresses only those claims involving a generic manufacturer's duty to change the *content* of the drug's labeling.

Furthermore, no Defendant took any steps to communicate the information in the FDA-approved label for metoclopramide to the medical community after 2002, the last time product information for the drug appeared in the *Physicians Desk Reference*. This included failing entirely to alert the proper parties that the warning for metoclopramide had been strengthened in 2004 to prohibit exposure to the drug longer than 12 weeks in duration. Where a plaintiff's labeling claims rest on an assertion that a defendant negligently failed to comply with duties equal to, or substantially identical to, requirements imposed under federal law, preemption does not preclude such claims. *See Medtronic v. Lohr*, 518 U.S. 470, 496 (1996).

E. TEXAS LAW

Very telling is the fact thatGeneric Defendants Motion does not cite a single Texas case identifying a cause of action that requires a manufacturer to change the content of the labeling of its products in order to comply with the state's laws. Rather, they seemingly ask the Court to determine that <u>all</u> of Plaintiff's claims require such action. As *Mensing* dealt only with one

particular theory in the context of a product liability claim, a discussion of Texas law regarding similar claims is appropriate. As Defendants have made no argument that Plaintiff's other causes of action are preempted, it is unclear on what basis their claim that all of Plaintiff's claims should be dismissed is premised.[16] Even so, as the laws of Texas do not *require* that a manufacturer change the content of its warning, but rather *prohibit* a manufacturer from selling a dangerous product without an adequate warning, Defendants' arguments are entirely misplaced.

This Court need look no further than the seminal case of *Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076 (5th Cir. 1973) to see the flaw in Actavis' argument. In *Borel*, the 5th Circuit examined Texas product liability claims against an asbestos manufacturer for injuries caused by its product in the context of strict liability, negligence and breach of warranty. At trial, the plaintiff introduced evidence that the defendant should have been aware of numerous studies and articles on asbestosis, that no manufacturer provided any warning regarding the dangers presented by use of the product, and that the defendant manufacturers had failed to test the effect of their products on the individuals using them, or to determine the level of risk posed by use of the product. *Borel*, 493 F.2d at 1086.

The plaintiff sought to hold the manufacturers liable for negligence, gross negligence, breach of warranty and strict liability. *Id.* The negligent acts alleged in the complaint were: (1) failing to take reasonable precautions or to exercise reasonable care to warn of the danger to which he was exposed in using the defendants' products; (2) failing to inform the plaintiff as to the appropriate measures to be taken to minimize risks posed by the product; (3) failing to test

[16] While Defendants have asserted that the all of Plaintiff's claims are preempted because their claims *involve* Defendants' failure to warn, as addressed above, the descriptive term applied to a claim is irrelevant to a preemption analysis. Furthermore, Plaintiff has clearly alleged, not only that Defendants failed to provide adequate warnings, but that they actively participated in concealing important information regarding the safety of their drug, that they invited long-term use of the drug for which it was unsuitable, and that they sold and distributed metoclopramide with information that dramatically understated the drug's risks, along with failing completely to comply with regulations designed to protect the safety of consumers.

the products in order to ascertain the dangers involved in their use; and (4) failing to remove the products from the market upon discovering the dangers they posed. *Id.* The plaintiffs also alleged that defendants' products were unreasonably dangerous because of the failure to provide adequate warnings of foreseeable dangers associated with their use. *Id.*

In analyzing the issues before it, the *Borel* Court engaged in an extensive analysis of Texas product liability law, first addressing strict liability:

> The requirement that the defect render the product 'unreasonably dangerous' reflects a realization that many products have both utility and danger. The determination that a product is unreasonably dangerous, or not reasonably safe, means that, on balance, the utility of the product does not outweigh the magnitude of the danger. The fulcrum for this balancing process is the reasonable man as consumer or as seller. Thus, a product is unreasonably dangerous only when it is 'dangerous to an extent beyond that contemplated by the ordinary consumer who purchases it'**.** ***In other words, for a product to be unreasonably dangerous, 'it must be so dangerous that a reasonable man would not sell the product if he knew the risk involved'***.

Borel, 493 F.2d at 1087-1088(emphasis added, internal citations omitted).

The court next discussed liability in the context of those products which are "unavoidably unsafe":

> 'unavoidably unsafe products' are those which, in the present state of human knowledge, are incapable of being made safe for their ordinary and intended use. Strict liability may not always be appropriate in such cases because of the important benefits derived from the use of the product. This is especially so with respect to new drugs that are essential in treating disease but involve a high degree of risk. It may also be so with respect to other commercial products possessing both unparalled utility and unquestioned danger. As a practical matter, ***the decision to market such a product requires a balancing of the product's utility against its known or foreseeable danger***. But, as comment k makes clear, even when such balancing leads to the conclusion that marketing is justified, the seller still has a responsibility to inform the user or consumer of the risk of harm. The failure to give adequate warnings in these circumstances renders the product unreasonably dangerous.

Citing to the case of *Davis v. Wyeth Laboratories, Inc*., 399 F.2d 121 (9th Cir. 1968), the Court discussed product liability in the context of prescription drugs:

> In such cases, then, ***the drug is fit and its danger is reasonable only if the balance is struck in favor of its use***. Where the risk is otherwise known to the consumer, no problem is presented, since choice is available. ***Where not known, however, the drug can properly be marketed only in such fashion as to permit the striking of the balance***; that is, by full disclosure of the existence and extent of the risk involved.

493 F.2d at 1088-89 (emphasis added, internal citations omitted).

The court then turned its attention to certain duties imposed by Texas product liability law on a manufacturer:

> Furthermore, in cases such as the instant case, the manufacturer is held to the knowledge and skill of an expert. This is relevant in determining (1) whether the manufacturer knew or should have known the danger, and (2) whether the manufacturer was negligent in ***failing to communicate*** this superior knowledge to the user or consumer of its product. The manufacturer's status as expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby. But even more importantly, a manufacturer has a duty to test and inspect his product. The extent of research and experiment must be commensurate with the dangers involved. ***A product must not be made available to the public without disclosure of those dangers that the application of reasonable foresight would reveal***. ***Nor may a manufacturer rely unquestioningly on others to sound the hue and cry concerning a danger in its product. Rather, each manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.***

493 F.2d at 1089-90 (emphasis added, internal citations omitted). The Court also discussed the effect of an intermediary on these duties:

> The seller's warning must be reasonably calculated to reach such persons and the presence of an intermediate party will not by itself relieve the seller of this duty. In general, of course, a manufacturer is not liable for miscarriages in the communication process that are not attributable to his failure to warn or the adequacy of the warning. This may occur, for example, where some intermediate party is notified of the danger, or discovers it for himself, and proceeds deliberately to ignore it and to pass on the product without a warning. But there is nothing in the trial court's charge in the present case to imply that the seller or manufacturer would be liable in such a situation.

493 F.2d at 1091-92.

On rehearing, the defendant manufacturers argued that the Court's determination that they had provided no warning to the plaintiff was erroneous, as the labels for their products had

indicated that inhalation of asbestos over long periods of time "may be harmful," that users should "avoid breathing the dust" and instructed users to wear respirators in situations lacking inadequate ventilation. *Id* at 1104. The 5th Circuit rejected this argument finding that:

> the jury could have concluded that the 'cautions' were not warnings in the sense that they adequately communicated to Borel and other insulation workers knowledge of the dangers to which they were exposed so as to give them a choice of working or not working with a dangerous product.

Id. The court went on to note that whether inclusion of information in a product's label actually constituted a "warning" was a question for the jury to decide, and that a finding that the label did not serve as a warning was not incorrect as a matter of law. *Id* at 1105.

V. CONCLUSION

For those reasons set out above, Plaintiffs requests that Generic Defendants' Motion to Dismiss be denied. Additionally, Plaintiffs believes the Court may benefit from oral argument regarding the issues discussed above, and respectfully requests that the Court schedule a hearing for this purpose.

Respectfully submitted this 21st day of October, 2011,

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